REMARKS/ARGUMENTS

Reconsideration of this patent application is respectfully requested in view of the foregoing amendments, and the following remarks. Claims 1-11 and 14-15 are in the application. Claims 1, 4, 5, 11 and 14 have been amended. No new matter has been added.

The Examiner rejected claims 1-9, 11 and 14 under 35 USC §112, stating that "an effective amount" is indefinite. Applicant has amended claims 1 and 11 to specify that the alpha CD is present in an amount of 1-15% (w/w). Support for this amendment can be found in the specification on page 18, second full paragraph. Claim 14 has been amended to specify that the amount is a weight percent. Claims 4 and 5 have been amended to be consistent with amended claim 1.

The Examiner rejected claims 1-11 and 14-15 under 35 USC §103(a) as being unpatentable over Artisa et al. in view of Suzuki et al. and further in view of Mayer Davis, International Diabetes Foundation and Van Laere et al. Applicants respectfully traverse.

The Examiner states that Artisa discloses a composition and method that relate to fat-containing consumable food and that Artisa does not teach reducing the glycemic index of food (see page 5 of the office action). The Examiner then states that Suzuki discloses that alpha CD and compositions with alpha CD as a major component have specific biological effects. One of these effects is the body weight gain suppression and body weight reduction and suppression of blood triglyceride concentration. He further states that Suzuki discloses that alpha CD has an inhibitory effect on body weight gain and is administered food at 12 to 25 g/kg body weight for the total Cyclodextrin or at 6-13 g/kg body weight for the alpha CD (see page 5 lines 7 and 8 from the bottom). This means for a 60 kg person, 720 to 1500 g cyclodextrin or 360 to 780 g alpha CD are added to the food. This means that a major part of the food intake consists of CD/alpha CD. From these disclosures, the Examiner concludes that it is apparent that alpha CD inherently reduces the glycemic index of food comprising alpha CD.

This conclusion is not correct. Suzuki teaches the reduction of body weight by uptake of alpha CD. Because one of skill in the art is aware that alpha CD has a low caloric

content, it is not at all astonishing that a food which is an alpha CD or a composition with alpha CD as major component leads to a reduction in body weight. Suzuki teaches to lower the uptake of calories by eating much of the low caloric alpha CD. It is common knowledge and the basis of nearly every diet that a lowered caloric uptake results in a loss of body weight.
But this fact is completely different to the teaching of the present application, that a combination of food with a defined small amount (1 to 15% of the food weight) of alpha CD results in a lowering of the glycemic index after uptake of the food. As the food is eaten in the same amount with and without alpha CD, the low caloric content of alpha CD does not play a role in the effect noticed according to the invention. Because the calories of the food remain unchanged, the food according to the invention comprises some further calories (due to the added alpha CD) and therefore even more calories are taken up by the food according to the present invention. Nevertheless, the glycemic index is lowered by this food. In this respect, see example 1 of the specification, which shows the results of an uptake of 100 g bread with and without a CD-containing beverage.

On page 5 of the office action, the Examiner cites the

teaching of Mayer-Davis that lifestyle changes can improve glucose tolerance at individuals at high risk for developing type 2 diabetes and that a reduced fat diet may result in improvements in the glycemic status after 5 years.

Mayer Davis teaches that lifestyle changes can improve glucose tolerance at individuals at high risk for developing type 2 diabetes. This has nothing to do with the addition of alpha CD to food. Mayer Davis further teaches that a reduced fat diet may result in improvements in the glycemic status after 5 years. This has nothing in common with the finding of the present invention that after the uptake of food having a GI, an immediate significant lowering of the blood glucose level is found if the food comprises a defined amount of alpha CD. An effect that "may be found after 5 years" can not make obvious an effect that is found within 1 to 2 hours after a meal (see figures 1 and 2 of the present application). The present invention relates to the lowering of the glycemic index of food. The glycemic index correlates to the starch content of the food, because the starch content of the food leads to an increase of the glucose content in blood. As said on page 2 last paragraph of the application, the glycemic index (GI) is a measure of the blood glucose rising

property of food. It is determined by analyzing the blood glucose levels in regular intervals for a 2-3 hour period after intake of the test food and a reference food which, by convention, is either white bread or glucose. Any teaching related to reduction of the absorption of fat has nothing to do with the present invention and also the teaching that after 5 years something may happen if the lifestyle is changed, cannot make a concrete teaching obvious how to reach a lowered glucose concentration in blood after hours.

The examiner further cites the finding of the International Diabetes Federation that weight loss can reduce insulin resistance and that blood glucose can be controlled with a low fat diet. This may be correct, but there is no connection with the present application or any of the cited references. Artisa does not teach a low fat diet, so a combination of Artisa and the finding of the International Diabetes Federation is not possible and does not make the present invention obvious.

On page 6 of the office action, the examiner states that Van Laere discloses by the citation of US 4,396,602 a method for lowering the blood glucose level in mammals. The method of US

4,396,602 comprises administering an enzyme which is capable of producing low digestible carbohydrates from high digestible carbohydrates and therefore the method results in lowering the blood glucose level. Enzymes providing such an effect are cyclodextrin synthesizing enzymes.

The present invention does not comprise enzymes. According to the present invention, alpha cyclodextrin, a slow digestible carbohydrate free of any enzymes, is used. According to the invention this carbohydrate is added to starch, a highly digestible carbohydrate, which adds even more carbohydrate to the composition. Nevertheless, the observed effect in human clinical studies shows a decrease in blood glucose level, not an increase, which would be expected by adding (even a slow) digestible carbohydrate. In the present application, no sugar is replaced and no enzyme is added.

The Examiner also rejected claims 1-11 and 14-15 under 35 USC §103 as being unpatentable over Artisa et al. in view of Van Laere et al. and Augustine et al. Applicant respectfully traverses.

Artisa shows the inhibition of fat by complexation with alpha CD. Fat is a hydrophobic compound and is able to be complexed by cyclodextrins. The teaching of the present application relates to an effect on glucose, starch or other carbohydrates. These compounds are hydrophilic compounds and therefore not likely to be complexed at all. Starch has additionally a much higher molecular weight as a polymer than CD itself. So also from this point of view, the decrease of absorption of fat (or reduced bioavailability) cannot explain the reduction of blood glucose response of starch-containing food.

Augustine states correctly that low glycemic index food characterized by slowly absorbed carbohydrates have been shown to produce a beneficial effect on glucose control. But according to the present invention, the carbohydrates are unchanged, starch remains starch, a highly digestible carbohydrate, because no enzymes are present to perform any reaction. Therefore, the teaching of Augustine et al. is not relevant for the present invention, because according to the present invention, the food remains unchanged, only alpha CD is added in small amounts and this addition has an unexpected effect.

JP0401 1865 describes a Gymnema Sylvestre (GS) cyclodextrin extract with no bitterness. GS extract and GS extract and CD showed that glucose in blood was significantly inhibited with GS preparations. Therefore the GS extract and not the CD is the active part of the formulation. CD is added to mask the bitterness of the extract. Moreover JP0401 1865 describes the addition of alpha-CD to a drug, not a food. Alpha-CD is added to extracts of Gymnema for an organoleptic purpose, and not for any potential glycemia-lowering effect. Finally, claim 1 of the present application pertains to the addition of alpha-CD to a food which has a glycemic index, i.e.. produces a glycemic response. This condition is, however, not fulfilled for Gymnema extracts, which do not contain glycemic carbohydrates. For all these reasons, this reference is not relevant for the claims of the present application.

Accordingly, Applicants submit that claims 1-11 and 14-15 are patentable over the cited references, taken either singly or in combination. Early allowance of the amended claims is respectfully requested.

Respectfully submitted,
Gerhard SCHMID ET AL.

COLLARD & ROE, P.C.
1077 Northern Boulevard
Roslyn, New York 11576
(516) 365-9802

Elizabeth C Richter, Reg. No. 35,103
Attorney for Applicants

ECR:cmm

Enclosures: Copy of Petition for one-month Extension of Time

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, Alexandria, VA, on July 17, 2008.

Amy Klein

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